The appeal claims relate to a method for the therapeutic use of novel formulations of the combination carbidopa-levodopa in the treatment of Parkinson's disease.

Issues

All of the appealed claims (1-2, 5, 8, and 11-16) are rejected under 35 USC 103 as being unpatentable over the combined teachings of Dempski et al (US Pat No 4, 900, 755, collectively "Dempski) and Conte et al (US Pat No 5, 738, 874, collectively "Conte").

Grouping of Claims

The ground of rejection, 35 USC 103, applies to all of the appealed claims (1-2, 5, 8, and 11-16).

Argument

The appealed Claims 1-2, 5, 8, and 11-16 have been rejected under 35 USC 103 as unpatentable over the cited references.

All of the claims are directed to the treatment of Parkinson's disease by administering novel formulations of the combination carbidopa-levodopa.

Facsimile Transmittal Sheet

To: BRIAN SEIDLECK

Location: GROUP ART UNIT : 1615

FAX Number: 703, 305-3592 Number of Pages

Date: 12/13/95 Including Cover Sheet: 4

From: ALAN RUBIN

Location: WILMINGTON. DE

Telephone No.: 302, 478-0538

NOTES:

AS PER OUR PHONE CONVERSATION THIS MORNING, I'M FAXING BRIEF TO YOUR OFFICE

GIL FATO WILL CALL TOMORROW.

Alan Rubin

16/Appeal Brief (1)

BRIEF FOR APPELLANT
SERIAL NO.: 08/835,482
CASE NO. 002

Ref 2-7-0

The examiner correctly states (paper 11) that "the combination of levodopa and carbidopa in a sustained release formulation is well known in the art". Dempski discovered a controlled release form of carbidopa-levodopa which prolonged pharmacologic activity and produced less variation in plasma levodopa levels than conventional carbidopa-levodopa (US Pat No 4, 900, 755, col 2, lines 18-42). The present invention summarizes these beneficial effects in the specification at pp 1 and 2 but also identifies a flaw in the Dempski formulation, ie, the serious delay in onset of action of controlled release carbidopa-levodopa. Correction of this flaw via formulations which combine rapid onset with controlled release carbidopa-levodopa is clearly set forth in the passage on p. 2, lines 13-29 of the present specification and in the examples on pp. 3-5.

It is also the examiner's position, correctly, that "the prior art teaches formulation comprising multiple release layers to provide for immediate and sustained release of actives, including levodopa and carbidopa". Conte claims a tablet containing immediate and slow drug release components. In his specification (col 2, lines 3-6), Conte states that "the prior art does not envisage the possibility of obtaining products capable of releasing one or more drugs at different rates or else of releasing two different drugs sequentially". And yet the prior art contains numerous examples of one or more drugs released at different rates and of two drugs released sequentially. For example, Lin et al (J. Int. Med. Res. 10(2):126-128, 1982) describe the release of d-pseudoephedrine sulfate from the outer coat and inner core of a repeat action tablet and Nomeir et al (J. Clin. Pharmacol. 36(10):923-930, 1996) report on the sequential release from 2-layer tablets of immediate release loratadine followed by extended release pseudoephedrine. Could Conte have been unaware of the prior art that invalidates the novelty of his release profile?

The examiner indicates that Conte "teaches a pharmaceutical tablet capable of releasing one or more drugs at different release rates.....The first contains one or more drugs with an immediate release profile and a second layer containing one or more drugs with a sustained release profile". But if the prior art covers this type of multiple release profile (see above), then Conte's novelty must lie elsewhere. The examiner also states that "Conte teaches combination therapy with both levodopa and carbidopa in a formulation with multiple release profiles". Yet Conte cites no valid, rational or original reason to use a multiple release format for carbidopa-levodopa. Instead, he repeats well known and established text book versions which describe (1) the metabolism of

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN THE APPLICATION OF:

ALAN A. RUBIN

CASE NO. 002

SERIAL NO.: 08/835,482

GROUP ART UNIT: 1615

FILED: APRIL 8, 1997

EXAMINER: BRIAN K. SEIDLECK

FOR: IMPROVEMENT IN TREATMENT OF PARKINSON'S DISEASE AND RELATED DISORDERS BY NOVEL FORMULATIONS OF THE COMBINATION CARBIDOPA-LEVODOPA

DATED: MAY 14, 1999

Assistant Commissioner for Patent

BRIEF FOR APPELLANT